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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,969	07/23/2003	Brent A. Johnson	17592 (AP)	1610

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	**PAPER NUMBER**
1617	
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10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,969	JOHNSON, BRENT A.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-44* is/are pending in the application.

4a) Of the above claim(s) *44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed August 1, 2007 presents remarks and arguments submitted to the office action mailed June 15, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 39-43 over over Shefer et al. (US 20030232091) in view Won et al. (US 5,955,109), Shalita et al. (Tazarotene gel is safe and effective in the treatment of acne vulgaris: a multicenter, double-blind, vehicle-controlled study. Cutis. 1999 Jun; 63 (6):349-54), and Sefton (US 6262117—previously presented) is not persuasive. Therefore, the rejection is maintained for the reasons of record.

Applicant's amendments of claim 39 submitted August 1, 2007 is acknowledged. Claims 39-43 are herein acted on the merits.

In view of applicants amendments the following modified 35 U.S.C. 103 (a) rejection is made:

Claim Objections

Claim 44 is objected to because of the following informalities: the status identifier is wrong. Should read – Previously presented - withdrawn. Appropriate correction is required.

Claim Rejections- 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shefer et al. (US 20030232091) in view Won et al. (US 5,955,109), Shalita et al.

(Tazarotene gel is safe and effective in the treatment of acne vulgaris: a multicenter, double-blind, vehicle-controlled study. Cutis. 1999 Jun; 63 (6):349-54), and Sefton (US 6262117—previously presented)

Shefer et al. teaches a controlled release system composition comprising a plurality of particles having retinol and other cosmetic, dermatological, and pharmaceutical active agents (p 16 [0187] claims 1 and 7). Active agents comprise one or more agents selected from the group inclusive of anti-acne agents and anti-wrinkle agents. Anti- acne agents are inclusive of antibiotics and antimicrobials such as benzoyl peroxide (p 8 [101]). Anti-wrinkle agents are inclusive of tazarotene(p 8-9 [103]). The composition particle or micro-sphere has a diameter of from about 0.1 to about 500 microns (p 17 claim 30). Suitable solid core materials for forming microspheres or particles of the present invention are inert nontoxic hydrophobic materials with a melting point range between about 30 degrees C and about 120 degrees C. Examples of hydrophobic materials include natural, regenerated, or synthetic waxes including: animal waxes such as beeswax, lanolin and shellac wax; vegetable waxes such as carnauba, candelilla, sugar cane, rice bran, and bayberry wax; mineral waxes such as petroleum waxes including paraffin; and microcrystalline wax, ozokrite wax, polyethylene wax, and mixtures thereof. Other hydrophobic materials which can be used in the present invention include wa x and silicon copolymers, such as candelilla wax and silicone copolymer, ozokrite wax and silicon copolymers, beeswax and silicon copolymers, and the like. Other hydrophobic compounds which can be used in the present invention include: fatty acid esters such as cetyl palmitate, ethyl

stearate, isopropyl myristate, and isopropyl palmitate; high molecular weight fatty alcohols such as cetostearyl alcohol, cetyl alcohol, stearyl alcohol, and oleyl alcohol, solid hydrogenated castor and vegetable oils, hard paraffins, hard fats, and mixtures thereof... (p 6-7 [0089] and p 16 claim 2).

Example 7 specifically teaches that the retinol is in fact encapsulated whereas the other active agent is not; hence, reading on the limitation a multiplicity of solid particles containing tazarotene but not benzoyl peroxide (p 15 [0181]).

Shefer does not exemplify a composition comprising tazarotene and benzoyl peroxide.

Won et al. teaches in the background of the invention that retinoids rapidly degrade and lose activity in typically formulated creams, ointments, oils, and the like. "In addition, moderate to severe skin irritation frequently results from the use of these formulations." Won et al. has cured these deficiencies by inventing a novel encapsulate controlled release composition of retinoids.

Shalita et al. is solely used to show tazarotene is a retinoid that acts against several factors that contribute to acne vulgaris.

Sefton teaches in the background of the invention that "Benzoyl peroxide has been suggested for treating acne vulgaris. (See U.S. Pat. No. 4,387,107.) For many years, benzoyl peroxide has been proven to be a particularly powerful keratolytic and anti-seborrhic agent, as well as being endowed with antibacterial properties. Topical benzoyl peroxide compositions, including a vehicle to enhance the efficacy thereof, are known (See U.S. Pat. No. 4,411,893). Topical compositions of benzoyl peroxide

combination with antibiotics are also known. (See U.S. Pat. Nos. 4,407,794; 4,692,329 and 4,387,107)

Peroxides, other than benzoyl peroxide, have been suggested for treatment of acne vulgaris, alone, or in combination with other compounds useful in treating acne vulgaris. (See U.S. Pat. Nos. 4,607,101 and 4,906,617.) These peroxides are suggested as having certain advantages, e.g. stability over benzoyl peroxide. U.S. Pat. No. 4,671,956 identifies the problem of benzoyl peroxide decomposing coingredients in topical formulations to thereby cause itching upon application. It is suggested that this problem may be solved by including a sunscreen in the topical formulation to retard this decomposition effect of benzoyl peroxide." (col 1 lines 43-65)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Shefer et al. in making a composition comprising a multiplicity of solid particles containing tazarotene and benzoyle peroxiede. The motivation to make such a composition is because (1)Shefer et al. teaches a controlled release system composition comprising a plurality of particles having retinol and other cosmetic, dermatological, and pharmaceutical active agents (p 16 [0187] claims 1 and 7). Active agents comprise one or more agents selected from the group inclusive of anti-acne agents and anti-wrinkle agents. Anti- acne agents are inclusive of antibiotics and antimicrobials such as benzoyl peroxide (p 8 [101]). Anti-wrinkle agents are inclusive of tazarotene(p 8-9 [103]). (2) Additionally, Shalita et al. teaches tazarotene is a retinoid that acts against several factors that contribute to acne vulgaris and (3) Won et al. teaches in the background of the invention that retinoids

rapidly degrade and lose activity in typically formulated creams, ointments, oils, and the like. "In addition, moderate to severe skin irritation frequently results from the use of these formulations." (4) Sefton teaches in the background of the invention that "Benzoyl peroxide has been suggested for treating acne vulgaris and identifies the problem of benzoyl peroxide decomposing coingredients in topical formulations to thereby cause itching upon application. Therefore, a skilled artisan would have had reasonable expectation of successfully producing a composition with controlled, continous release of effective levels of retinol and other active agents over an extended period of time useful in treatment of acne vulgaris.

Response to Arguments

Applicant's arguments filed August 1, 2007 have been fully considered but they are not persuasive for the reasons set forth below.

Applicant argues that " None of the references teach or suggest the desirablility of the multiplicity of solid particles not containing benzoyl peroxide. In fact, the Office Action suggests the opposite by stating "a skilled artisan would have reasonable expectation of successfully producing a composition with controlled continuous, release of effective levels of retinol and other active agents over an extended period of time." This seems to indicate that the Office reads the prior art to suggest putting the retinol (tazarotene) with the other active agent (benzoyl peroxide) into the particles to achieve sustained release. But in the claims as amended, benzoyl peroxide is excluded from the particles, thus thwarting the purpose of achieving sustained release. Therefore, the claims are not obvious." However, Examiner respectfully reiterates

Example 7 specifically teaches that the retinol is in fact encapsulated whereas the other active agent is not; hence, reading on the limitation a multiplicity of solid particles containing tazarotene but not benzoyl peroxide (p 15 [0181]). Additionally, as the claim reads, the benzoyl peroxide is not excluded from the particles but is excluded from mixing with the tazarotene, which is obviated by the teachings of the prior art, as stated in the rejections above.

The arguments are not persuasive and the rejection is made **FINAL**.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER